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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------|------------------|
| 09/976,798   | 10/12/2001  | Joseph C. Trautman   | ARC 3043 R1               | 2432             |
| 7590 06/23/2005  |             |                      | EXAMINER                  |                  |
| FRANCIS LAW GROUP<br>1942 EMBARCADERO<br>OAKLAND, CA 94606 |             |                      | WILLIAMS, CATHERINE SERKE |                  |
|  |             |                      | ART UNIT                  | PAPER NUMBER     |
|  |             |                      | 3763                      |                  |

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/976,798

Applicant(s)

TRAUTMAN ET AL.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 40-52 is/are pending in the application.
- 4a) Of the above claim(s) 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 46-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The objection to the drawings received 7-15-04 has been removed in light of the cancellation of new figure 8.

### ***Specification***

The objection to the specification under 35 U.S.C. 132 has been withdrawn in light of the withdrawal of the previous amendment to the specification.

### ***Claim Objections***

Claim 50 is objected to because of the following informalities: the recites "applying a hold down force...in the range of 0.5-1 kg" however these units are not units of force but rather mass. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 46-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/09184 in view of Kheiri et al (USPN 6,364,889). WO 00/09184 ('184) discloses an apparatus for delivering a substance having one or more needles driven at a high velocity for

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reducing the amount of pain experienced by the recipient of the substance. The device includes microprotrusions (see figure 5) that transfer an agent into a microslit (inherent) formed in the skin by the microprotrusions. See page 7 lines 8+. The needles are driven by an impact applicator at a velocity of 1-100 m/s into the skin. See page 2 lines 10+. This velocity along with the disclosed mass of the needle and moving parts at preferably 0.3-1 g will result in the claimed energy on impact of 0.05-3 Joules/cm<sup>2</sup>. Agents that can be transferred include drugs, vaccines, etc. The needles are designed to penetrate to a depth of 10 microns.

'184 meets the claim limitations as described above but fails to include striking the stratum corneum in no greater than 10 ms.

However, Kheiri discloses an electronic lancing device that includes the teaching of having an in-stroke portion of a lancing being about 10ms for reducing the pain experienced by the user.

At the time of the invention, it would have been obvious to incorporate the teaching of Kheiri regarding the timing of the in-stroke into the invention of '184 since both devices teach ways to reduce pain to the subject of the device. The motivation for making the incorporation can be found in the overall teaching of '184 in that the entire device and method of using is to reduce the pain experienced by the patient. By incorporating the teaching of Kheiri, the objectives of '184 would be enhanced.

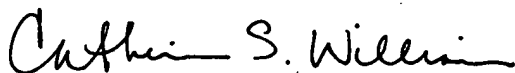
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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams  
June 22, 2005